
CLAIMS

[Claim(s)]

[Claim 1] eyewashing of a unit dose form -- eyewashing which contains a drug at least in a cup -- eyewashing characterized by coming to have liquid and having a film-like covering device further -- tools.

[Claim 2] eyewashing according to claim 1 whose drug is at least one sort of resolution and an astringent, an antihistamine, vitamins, and amino acid -- tools.

[Claim 3] fatty tuna -- eyewashing including a meta-mall according to claim 1 or 2 -- tools.

[Claim 4] eyewashing -- eyewashing given in either of claims 1-3 which light transmittance [in / in a cup / the wavelength of 200nm - 380nm] becomes from 10% or less of flexible material -- tools.

[Claim 5] eyewashing given in either of claims 1-4 in which a covering device contains the layered product of a resin sheet layer and an aluminium sheet layer -- tools.

[Claim 6] eyewashing given in either of claims 1-5 by which the light transmittance in the wavelength of 200nm - 380nm was packed with 10% or less of package object -- tools.

[Claim 7] dry eye, an allergic eye disease, and the time of contact lens wearing -- eyewashing given in either of claims 1-6 of ** used in either at least -- tools.

DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention] this invention -- eyewashing -- eyewashing which contains a drug in more detail about tools -- liquid -- eyewashing of a unit dose form (1-time using-up type) -- eyewashing with which it was filled up in the cup -- it is related with tools.

[0002]

[Description of the Prior Art] Eyewashing is one of the methods of dealing with the eye disease therapy currently performed conventionally or prevention, and aims at washing and sterilization in the saccus conjunctivae, eye disease prevention, etc. eyewashing used for eyewashing -- if liquid is roughly classified, the mineral and the germicide

content type (type which uses germicides, such as mineral, such as a sodium chloride, potassium chloride, and a boric acid, and alkylpolyamino ethylglycine, as a principal component) which makes washing and sterilization of an eye a key objective, and two types of drug content type (type which uses resolution and astringent, antihistamine, vitamin, and amino acid as principal component) ** which makes eye disease prevention a key objective will be mentioned. The collyrium of the type which contains mineral, a germicide, etc. only for the purpose of washing or sterilization was in use conventionally also in these types of inside. However, since people with allergy by multiple use of OA equipment, such as a fatigue eye, a dry eye patient and the wearing person of a contact lens, and pollinosis, etc. increased very much with technical development etc. in recent years, an eye disease is prevented and the drug content type which made aggravation prevention of the further symptom the key objective is spreading quickly.

[0003] these drug content type eyewashing -- the liquid user etc. has received the damage in the eye in many cases, and is very sensitive to the stimulus. therefore, eyewashing to be used -- as for liquid, it is desirable to design so that the component which is stimulative to an eye as much as possible may not be blended. However, although the antiseptics used conventionally did not become [as opposed to / especially / the healthy eye] a problem, they are matter which gives a stimulus to eye membrane, and to the sensitive eye which received the damage, especially a stimulus is strong and they had a problem, in order to prevent the microbial contamination of pharmaceutical preparation.

[0004] on the other hand -- these eyewashing -- liquid -- usually -- eyewashing -- the collyrium bottle filled up with liquid, and eyewashing -- a cup markets as a set -- having -- **** -- eyewashing -- eyewashing of suitably the attachment by liquid -- it is used, subdividing into a cup. therefore, eyewashing -- since the cup was repeatedly used after washing, avoiding contamination had a problem difficultly. especially -- eyewashing -- since there was much matter used as a bacterial suitable nutrient in the drug contained in liquid, bacterial propagation had become a big problem. therefore -- above -- eyewashing -- there was a problem that antiseptics exciting against liquid had to be blended.

[0005]

[Problem(s) to be Solved by the Invention] This invention solves many problems in said former, and makes it a technical problem to attain the following purposes. since [namely,] it does not have contamination since a cup does not need to be repeated and used for this invention, and safety is high and does not need to blend antiseptics further

-- an eye -- receiving -- eyewashing of a low stimulus -- it aims at offering tools.

[0006]

[Means for Solving the Problem] As said The means for solving a technical problem, it is as follows. <1> eyewashing of a unit douse form -- eyewashing which contains a drug at least in a cup -- eyewashing characterized by coming to have liquid and having a film-like covering device further -- they are tools. [namely,]

<2> eyewashing given in the above <1> whose drug is at least one sort of resolution and an astringent, an antihistamine, vitamins, and amino acid -- they are tools.

<3> fatty tuna -- eyewashing the above <1> including a meta-mall, or given in <2> -- they are tools.

<4> eyewashing -- eyewashing given in either of the above <1> with which light transmittance [in / in a cup / the wavelength of 200nm - 380nm] consists of 10% or less of flexible material to <3> -- they are tools.

<5> eyewashing given in either of the above <1> with which a covering device contains the layered product of a resin sheet layer and an aluminium sheet layer to <4> -- they are tools.

<6> eyewashing given in either of the above <1> by which the light transmittance in the wavelength of 200nm - 380nm was packed with 10% or less of package object to <5> -- they are tools.

<7> dry eye, an allergic eye disease, and the time of contact lens wearing -- eyewashing given in either of the above <1> of ** used in either at least to <6> -- they are tools.

[0007]

[Embodiment of the Invention] Hereafter, this invention is explained to a detail. eyewashing of this invention -- tools -- eyewashing of a unit douse form -- the inside of a cup -- eyewashing -- it comes to have liquid, has a film-like covering device further, and has other members etc. if needed.

[0008] [-- eyewashing -- cup] -- said eyewashing -- a cup -- eyewashing of a unit douse form -- it is a cup. this -- eyewashing -- as the magnitude and the configuration of a cup -- eyewashing -- although there will be especially no limit if it is the design which liquid does not leak but is suitable for carrying out eyewashing, it is desirable that it is the configuration in which the opening circumference is the magnitude of extent which can cover an eye socket, and fits the eye socket periphery section.

[0009] said eyewashing -- as the quality of the material of a cup, although various synthetic resin and a natural resin material can be used, if the application etc. is taken into consideration, the resin currently used as a medical high polymer ingredient is desirable. Moreover, you may be resin with which antibacterial was given.

[0010] as said medical high polymer ingredient -- a polyvinyl chloride (PVC) (hard --) Elasticity, ABS plastics (a general purpose, fire retardancy), polyethylene, a polycarbonate, Ethylene vinyl acetate (EVA), polypropylene, polystyrene, Synthetic rubber, natural rubber, methacrylic resin, silicone, silicone rubber, Polyurethane, polymer gel (nature, artificiality), Pori 3 fluoride ethylene, Thermoplastic elastomer (TPE), polyvinyl alcohol, polytetrafluoroethylene, An epoxy resin, polyethylene terephthalate, a polyamide, polyacetal, polyvinylidene fluoride, a urea-resin, phenol resin, alkyd resin, melamine resin, a cyano chestnut rate, acrylic resin, etc. are desirable. Also in these, polyethylene, ethylene vinyl acetate, polypropylene, polyethylene terephthalate, natural rubber, synthetic rubber, silicone, a polyvinyl chloride, methacrylic resin, silicone rubber, polyurethane, a polycarbonate, polymer gel (nature, artificiality), especially Pori 3 fluoride ethylene, etc. are especially desirable.

[0011] said eyewashing -- as the quality of the material of a cup -- eyewashing -- if the stability of the drug in liquid is taken into consideration, it is desirable that the light transmittance in the wavelength of 200-380nm uses 10% or less of flexible material, and it may use especially titanium oxide, a zinc oxide, an ultraviolet-rays inhibitor and the resin that kneaded coloring matter, and resin and the laminated plastic of the light transmission prevention layer containing said matter (titanium oxide, a zinc oxide, an ultraviolet-rays inhibitor, coloring matter, etc.). said eyewashing -- as the thickness of a cup -- eyewashing -- when the operability at the time etc. is taken into consideration, it is desirable that it is 0.01mm - 1mm.

[0012] [-- eyewashing -- liquid] -- said eyewashing -- liquid contains other components at least if needed including a drug.

- Drug - As said drug, although there is especially no limit, resolution and an astringent, an antihistamine, vitamins, and amino acid are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0013] As said resolution and astringent, epsilon-aminocaproic acid, allantoin, berberine chloride, berberine sulfate, azulene sulfonate sodium, glycyrrhizinate dipotassium, a zinc sulfate, lactic-acid zinc, lysozyme chloride, etc. are mentioned, for example. said eyewashing of this resolution and astringent -- although there is especially no limit, if it is epsilon-aminocaproic acid as a content in liquid -- usually -- 0.01 - 5 w/v% ("mass / capacity %" is meant.) Hereafter, it is the same. It is desirable to make it contain and 0.1 - 0.5 w/v% is more desirable. If it is allantoin, it is desirable to usually carry out 0.001-0.3 w/v% content, and 0.005 - 0.03 w/v% is more desirable. If it is berberine chloride or berberine sulfate, it is desirable to usually carry out 0.0001-0.025 w/v% content, and 0.0005 - 0.0025 w/v% is more desirable. If it is azulene sulfonate sodium, it is desirable

to usually carry out 0.00005-0.02 w/v% content, and 0.0001 - 0.002 w/v% is more desirable. If it is glycyrrhizinate dipotassium, it is desirable to usually carry out 0.001-0.25 w/v% content, and 0.005 - 0.025 w/v% is more desirable. It is desirable to usually carry out 0.001-0.25 w/v% content of that with a zinc sulfate or lactic acid zinc, and 0.005 - 0.025 w/v% is more desirable. If it is lysozyme chloride, it is desirable to usually carry out 0.001-0.5 (potency) content, and 0.01-0.05 (potency) are more desirable. While the drug effect by making a drug contain if said content does not fulfill said desirable numerical range in each may not be obtained, when said desirable numerical range is exceeded, a feeling of use may be spoiled.

[0014] As said antihistamine, diphenhydramine hydrochloride, chlorpheniramine maleate, etc. are mentioned, for example. said eyewashing of these antihistamines -- as a content in liquid, although there is nothing, if especially a limit is diphenhydramine hydrochloride, it is desirable to usually carry out 0.0001-0.05 w/v% content, and it is more desirable. [0.001 - 0.005 w/v% of] If it is chlorpheniramine maleate, it is desirable to usually carry out 0.00001-0.03 w/v% content, and 0.0005 - 0.003 w/v% is more desirable. Unless said each content fulfills said desirable numerical range, while the drug effect by making a drug contain may not be obtained, when said desirable numerical range is exceeded, a feeling of use may be spoiled.

[0015] As said vitamins, flavin adenine dinucleotide sodium, cyanocobalamine, retinol acetate, retinol palmitate, pyridoxine hydrochloride, Panthenol, calcium pantothenate, sodium pantothenate, tocopherol acetate, etc. are mentioned, for example. eyewashing of these vitamins -- as a content in liquid, although there is nothing, if especially a limit is flavin adenine dinucleotide sodium, it is desirable to usually carry out 0.0001-0.05 w/v% content, and it is more desirable. [0.0005 - 0.005 w/v% of] If it is cyanocobalamine, it is desirable to usually carry out 0.0001-0.02 w/v% content, and 0.0002 - 0.002 w/v% is more desirable. If it is retinol acetate or retinol palmitate, 0.0001 - 0.2 w/v%, i.e., do 100-360000I.U. / 100mL content of, is usually desirable, and 0.001 - 0.03 w/v%, i.e., 1000-54000I.U./100mL, is more desirable.

[0016] As said retinol palmitate, the thing of 1 million to 1,800,000 international unit (following I.U. and brief sketch) is usually marketed, and, specifically, retinol palmitate 1,700,000I.U. (made in Roche vitamin Japan, Inc.) etc. is mentioned. As pyridoxine hydrochloride, it is usually desirable to carry out 0.0001-0.1 w/v% content, and 0.001 - 0.01 w/v% is more desirable. As Panthenol, calcium pantothenate, or sodium pantothenate, it is desirable to usually carry out 0.0001-0.1 w/v% content, and 0.001 - 0.01 w/v% is more desirable. If it is tocopherol acetate, it is desirable to usually carry out 0.0001-0.05 w/v% content, and 0.0005 - 0.005 w/v% is more desirable. Unless said

each content fulfills said each ** better ***** range, while the drug effect by making a drug contain may not be obtained, when said desirable numerical range is exceeded, a feeling of use may be spoiled.

[0017] As said amino acid, potassium L-aspartate, L-asparatic acid magnesium, aminoethylsulfonic acid, sodium chondroitin sulfate, etc. are mentioned, for example. eyewashing of these amino acid -- as a content in liquid, although there is nothing, if especially a limit is potassium L-aspartate or L-asparatic acid magnesium, it is desirable to usually carry out 0.005-1 w/v% content, and it is more desirable. [0.01 - 0.1 w/v% of] If it is aminoethylsulfonic acid, it is desirable to usually carry out 0.005-1 w/v% content, and 0.01 - 0.1 w/v% is more desirable. If it is sodium chondroitin sulfate, it is desirable to usually carry out 0.002-0.5 w/v% content, and 0.005 - 0.05 w/v% is more desirable.

[0018] - other component - as the component of said others -- eyewashing -- various kinds of additives, such as all the buffers usually used for preparation of liquid, a solubilizing agent, an isotonizing agent, a stabilizing agent, a viscous agent, a chelating agent, pH regulator, and a cool-ized agent, other pharmacological active principles, etc. are mentioned. These can usually be suitably blended in the amount used.

[0019] As said buffer, for example A boric acid or its salts (borax etc.), a citric acid, or its salt (sodium citrate etc.), a phosphoric acid or its salt (phosphoric acid 1 hydrogen sodium and a sodium dihydrogenphosphate --) Dibasic sodium phosphate, a sodium dihydrogenphosphate, a potassium dihydrogenphosphate, etc., Carbonic acid or its salt (a sodium carbonate, sodium hydrogencarbonate), a tartaric acid, or its salt (sodium tartrate etc.), a gluconic acid or its salts (sodium gluconate etc.), an acetic acid or its salt, various amino acid (sodium acetate etc.) (glutamic acid, sodium glutamate, etc.), and fatty tuna -- a meta-mall etc. is mentioned. These may be used by the one-sort independent and may use two or more sorts together. the inside of these -- especially -- a boric acid or its salts (borax etc.), and fatty tuna -- by using a meta-mall etc., since the preservation-from-decay effectiveness improves more, it is desirable. especially -- fatty tuna -- since there are few stimuli and the meta-mall has a good feeling of use, it is desirable.

[0020] As said solubilizing agent, polyoxyethylene sorbitan higher-fatty-acid ester, such as polyoxyethylene higher-fatty-acid ester, such as polyoxyethylene (p= 60) hydrogenated castor oil, and polyoxyethylene (p= 20) sorbitan monooleate, propylene glycol, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0021] As said isotonizing agent, a sodium chloride, potassium chloride, a glycerol, D-

mannitol, xylitol, grape sugar, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0022] As said stabilizing agent, disodium edetate, cyclodextrin, a sulfite, a citric acid or its salt, dibutylhydroxytoluene, etc. are mentioned, for example.

[0023] As said viscous agent, a polyvinyl pyrrolidone, hydroxyethyl cellulose, the hydroxypropyl methylcellulose, methyl cellulose, polyvinyl alcohol, hyaluronate sodium, sodium chondroitin sulfate, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0024] As said chelating agent, disodium edetate, a sodium citrate, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0025] As said pH regulator, a hydrochloric acid, a sodium hydroxide, a potassium hydroxide, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0026] As said cool-ized agent, menthol, camphor, a borneol, a geraniol, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0027] <many physical properties of a penetrant remover> -- said eyewashing -- as acidity or alkalinity (pH) of liquid, pH 5-8 is desirable and pH 5.5-8 is more desirable.

[0028] said eyewashing -- as an osmotic-pressure ratio of liquid, although there is especially no limit, it is desirable to adjust within the limits of 0.85-1.55 (osmotic-pressure ratio for a physiological saline).

[0029] said eyewashing -- as viscosity in 20 degrees C of liquid, although there is especially no limit, its 1 - 100 mPa·s is desirable, its 1 - 20 mPa·s is more desirable, and its 1 - 5 mPa·s is still more desirable.

[0030] a [covering device] -- said covering device -- the shape of a film -- it is -- said eyewashing -- the time of saving liquid -- this -- eyewashing -- liquid -- eyewashing -- it does not leak out of a cup -- as -- eyewashing -- it is desirable to have pasted the opening periphery upper limit of a cup with heat sealing, adhesives, etc. adhesion of a covering device -- the time of use -- eyewashing -- it is desirable to be made as [tear / from the body of a cup / it / easily], and it is more desirable to paste up in the range of peel strength 200 - 2000 g/cm extent with the class of adhesives or the thermal melting arrival temperature of heat sealing. As these adhesives, polyurethane adhesive etc. is desirable.

[0031] As the quality of the material of said covering device, others, an aluminium sheet, etc. which are various synthetic resin. a natural resin material, etc. are mentioned. as

resin, such as various synthetic resin and a natural resin material, -- said eyewashing -- the resin currently used as the same medical high polymer ingredient as the quality of the material of a cup described, the resin with which antibacterial was given are desirable. Especially as this covering device, the layered product of the resin sheet layer of these resin and an aluminium sheet layer is desirable. It is preferably [a thing with low permeability] as the quality of the material of said covering device, and specifically more desirable that the light transmittance in the wavelength of 200-380nm is less than 10%.

[0032] As thickness of the covering device of the shape of said film, although there is especially no limit, its about 0.03-0.5mm is desirable.

[0033] [other members] etc. -- as the member of said others etc. -- points, such as the stability of a drug, -- it is -- eyewashing -- the package object which packs tools is desirable. light transmittance [in / it is desirable to consist of the quality of the material with low light transmittance as this package object, and / the wavelength of 200-380nm] consists of the quality of the material which is 10% or less -- more -- desirable -- a package object -- eyewashing -- it is desirable that tools are especially packed according to an individual.

[0034] < -- eyewashing -- eyewashing of manufacture > this invention of tools -- as the manufacture approach of tools Although there is especially no limit, for example, add each combination component, such as a drug, to sterile purified water, and it dissolves. It carries out aseptic into a cup (for example, the product made from polyethylene; 2 mL). pH -- adjusting -- eyewashing -- eyewashing after preparing liquid -- furthermore, a film (film which laminated aluminium foil in the shape of sandwiches from both sides with the polyethylene film) -- eyewashing -- approaches, such as carrying out a heat sheet along with opening of a cup, are mentioned.

[0035] < -- eyewashing -- eyewashing of this invention explained more than >, such as an application of tools, -- tools -- eyewashing -- eyewashing which does not have worries about microbial contamination and was excellent in safety since needed to repeat a cup and it was not necessary to use it -- liquid can be offered. Moreover, from side effects, such as an eye stimulus by there being no need of blending antiseptics once since it is a using-up type, and making antiseptics contain, not arising, a stimulus is low also in the case of symptoms [, such as dry eye,], such as damage, inflammation, etc. of the eye especially produced from wearing of a contact lens, pollinosis, etc., and its safety and effectiveness are highly useful to it.

[0036]

[Example] Although an example and the example of a comparison are shown below and

this invention is concretely explained to it, this invention is not limited at all by these examples.

[0037] (Examples 1-2) a formula (loadings of each component: mg/100mL) given in Table 1 -- following -- each component -- sterile purified water -- adding -- dissolving -- pH -- adjusting -- eyewashing -- liquid was prepared. it was obtained -- each -- eyewashing -- the unit douse form made from polyethylene which sterilized 2ml of liquid -- eyewashing -- the film (what laminated aluminium foil in the shape of sandwiches from both sides with the polyethylene film, light transmittance in wavelength:200-380nm: 0%) which filled up the cup (wavelength: light transmittance:0% in 200-380nm, thickness:1.0mm) with the bottom of sterile, and sterilized further -- eyewashing -- it heat sealed so that **** of liquid might not happen. then, eyewashing after saving in one month and under a predetermined environment (25 degrees C, 60%RH, fluorescent lamp (1500LUX)) -- when evaluated about generating of the microorganism in liquid, and the stability of a drug, generating of a microorganism was not accepted but was good. [of the stability of a drug] Moreover, when I had ten persons' panelist use it, the stimulus carried out all ten evaluations that a feeling of use was good, without completely sensing.

[0038]

[Table 1]

[0039] (Examples 3-9) a formula (loadings of each component: mg/100mL) given in Table 2 -- following -- each component -- sterile purified water -- adding -- dissolving -- pH -- adjusting -- eyewashing -- liquid was prepared. it was obtained -- each -- eyewashing -- the product made from polyethylene which sterilized 2ml of liquid, and the product made from polypropylene -- the product made from polyethylene terephthalate, and the product made from ethylene vinyl acetate -- and each unit douse form made from a polycarbonate -- eyewashing -- a cup (light transmittance in the wavelength of 200-380nm: 0 to 5% altogether) thickness: -- the film (what laminated aluminium foil in the shape of sandwiches from both sides with the polyethylene film --) which filled up with the bottom of sterile in 1.0mm, and sterilized further light transmittance:0% in the wavelength of 200-380nm -- eyewashing -- it heat sealed so that the liquid spill of liquid might not happen. Then, it enclosed with the saccate package object of the polyethylene containing an ultraviolet-rays inhibitor. eyewashing after saving this in one month and under a predetermined environment (25 degrees C, 60%RH, fluorescent lamp (1500LUX)) -- the place evaluated about generating of the microorganism in liquid, and the stability of a drug -- which eyewashing -- also in tools. generating of a

microorganism was not accepted but was good. [of the stability of a drug] Moreover, when I had ten persons' panelist use it, the stimulus carried out all ten evaluations that a feeling of use was good, without completely sensing.

[0040]

[Table 2]

[0041] In Table 2, "*" shows the titer.

[0042]

[Effect of the Invention] since according to this invention there is no contamination since need to repeat a cup and it is not necessary to use it, and safety is high and it is not necessary to blend antiseptics further -- an eye -- receiving -- eyewashing of a low stimulus -- tools can be offered.

TECHNICAL FIELD

[Field of the Invention] this invention -- eyewashing -- eyewashing which contains a drug in more detail about tools -- liquid -- eyewashing of a unit dose form (1-time using-up type) -- eyewashing with which it was filled up in the cup -- it is related with tools.

PRIOR ART

[Description of the Prior Art] Eyewashing is one of the methods of dealing with the eye disease therapy currently performed conventionally or prevention, and aims at washing and sterilization in the saccus conjunctivae, eye disease prevention, etc. eyewashing used for eyewashing -- if liquid is roughly classified, the mineral and the germicide content type (type which uses germicides, such as mineral, such as a sodium chloride, potassium chloride, and a boric acid, and alkylpolyamino ethylglycine, as a principal component) which makes washing and sterilization of an eye a key objective, and two types of drug content type (type which uses resolution and astringent, antihistamine, vitamin, and amino acid as principal component) ** which makes eye disease prevention a key objective will be mentioned. The collyrium of the type which contains mineral, a germicide. etc. only for the purpose of washing or sterilization was in use

conventionally also in these types of inside. However, since people with allergy by multiple use of OA equipment, such as a fatigue eye, a dry eye patient and the wearing person of a contact lens, and pollinosis, etc. increased very much with technical development etc. in recent years, an eye disease is prevented and the drug content type which made aggravation prevention of the further symptom the key objective is spreading quickly.

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[0004] on the other hand -- these eyewashing -- liquid -- usually -- eyewashing -- the collyrium bottle filled up with liquid, and eyewashing -- a cup markets as a set -- having -- **** -- eyewashing -- eyewashing of suitably the attachment by liquid -- it is used, subdividing into a cup. therefore, eyewashing -- since the cup was repeatedly used after washing, avoiding contamination had a problem difficultly. especially -- eyewashing -- since there was much matter used as a bacterial suitable nutrient in the drug contained in liquid, bacterial propagation had become a big problem. therefore -- above -- eyewashing -- there was a problem that antiseptics exciting against liquid had to be blended.

EFFECT OF THE INVENTION

[Effect of the Invention] since according to this invention there is no contamination since need to repeat a cup and it is not necessary to use it, and safety is high and it is not necessary to blend antiseptics further -- an eye -- receiving -- eyewashing of a low stimulus -- tools can be offered.

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention] This invention solves many problems in said

former, and makes it a technical problem to attain the following purposes. since [namely,] it does not have contamination since a cup does not need to be repeated and used for this invention, and safety is high and does not need to blend antiseptics further -- an eye -- receiving -- eyewashing of a low stimulus -- it aims at offering tools.

MEANS

[Means for Solving the Problem] As said The means for solving a technical problem, it is as follows. <1> eyewashing of a unit dose form -- eyewashing which contains a drug at least in a cup -- eyewashing characterized by coming to have liquid and having a film-like covering device further -- they are tools. [namely,]

<2> eyewashing given in the above <1> whose drug is at least one sort of resolution and an astringent, an antihistamine, vitamins, and amino acid -- they are tools.

<3> fatty tuna -- eyewashing the above <1> including a meta-mall, or given in <2> -- they are tools.

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[0008] [-- eyewashing -- cup] -- said eyewashing -- a cup -- eyewashing of a unit dose form -- it is a cup. this -- eyewashing -- as the magnitude and the configuration of a cup -- eyewashing -- although there will be especially no limit if it is the design which liquid does not leak but is suitable for carrying out eyewashing, it is desirable that it is the

configuration in which the opening circumference is the magnitude of extent which can cover an eye socket, and fits the eye socket periphery section.

[0009] said eyewashing -- as the quality of the material of a cup, although various synthetic resin and a natural resin material can be used, if the application etc. is taken into consideration, the resin currently used as a medical high polymer ingredient is desirable. Moreover, you may be resin with which antibacterial was given.

[0010] as said medical high polymer ingredient -- a polyvinyl chloride (PVC) (hard --) Elasticity, ABS plastics (a general purpose, fire retardancy), polyethylene, a polycarbonate, Ethylene vinyl acetate (EVA), polypropylene, polystyrene, Synthetic rubber, natural rubber, methacrylic resin, silicone, silicone rubber, Polyurethane, polymer gel (nature, artificiality), Pori 3 fluoride ethylene, Thermoplastic elastomer (TPE), polyvinyl alcohol, polytetrafluoroethylene, An epoxy resin, polyethylene terephthalate, a polyamide, polyacetal, polyvinylidene fluoride, a urea-resin, phenol resin, alkyd resin, melamine resin, a cyano chestnut rate, acrylic resin, etc. are desirable. Also in these, polyethylene, ethylene vinyl acetate, polypropylene, polyethylene terephthalate, natural rubber, synthetic rubber, silicone, a polyvinyl chloride, methacrylic resin, silicone rubber, polyurethane, a polycarbonate, polymer gel (nature, artificiality), especially Pori 3 fluoride ethylene, etc. are especially desirable.

[0011] said eyewashing -- as the quality of the material of a cup -- eyewashing -- if the stability of the drug in liquid is taken into consideration, it is desirable that the light transmittance in the wavelength of 200-380nm uses 10% or less of flexible material, and it may use especially titanium oxide, a zinc oxide, an ultraviolet-rays inhibitor and the resin that kneaded coloring matter, and resin and the laminated plastic of the light transmission prevention layer containing said matter (titanium oxide, a zinc oxide, an ultraviolet-rays inhibitor, coloring matter, etc.). said eyewashing -- as the thickness of a cup -- eyewashing -- when the operability at the time etc. is taken into consideration, it is desirable that it is 0.01mm - 1mm.

[0012] [-- eyewashing -- liquid] -- said eyewashing -- liquid contains other components at least if needed including a drug.

· Drug · As said drug, although there is especially no limit, resolution and an astringent, an antihistamine, vitamins, and amino acid are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0013] As said resolution and astringent, epsilon-aminocaproic acid, allantoin, berberine chloride, berberine sulfate, azulene sulfonate sodium, glycyrrhizinate dipotassium, a zinc sulfate, lactic-acid zinc, lysozyme chloride, etc. are mentioned, for example. said eyewashing of this resolution and astringent -- although there is especially no limit, if it

is epsilon-aminocaproic acid as a content in liquid -- usually -- 0.01 - 5 w/v% ("mass / capacity %" is meant.) Hereafter, it is the same. It is desirable to make it contain and 0.1 - 0.5 w/v% is more desirable. If it is allantoin, it is desirable to usually carry out 0.001-0.3 w/v% content, and 0.005 - 0.03 w/v% is more desirable. If it is berberine chloride or berberine sulfate, it is desirable to usually carry out 0.0001-0.025 w/v% content, and 0.0005 - 0.0025 w/v% is more desirable. If it is azulene sulfonate sodium, it is desirable to usually carry out 0.00005-0.02 w/v% content, and 0.0001 - 0.002 w/v% is more desirable. If it is glycyrrhizinate dipotassium, it is desirable to usually carry out 0.001-0.25 w/v% content, and 0.005 - 0.025 w/v% is more desirable. It is desirable to usually carry out 0.001-0.25 w/v% content of that with a zinc sulfate or lactic acid zinc, and 0.005 - 0.025 w/v% is more desirable. If it is lysozyme chloride, it is desirable to usually carry out 0.001-0.5 (potency) content, and 0.01-0.05 (potency) are more desirable. While the drug effect by making a drug contain if said content does not fulfill said desirable numerical range in each may not be obtained, when said desirable numerical range is exceeded, a feeling of use may be spoiled.

[0014] As said antihistamine, diphenhydramine hydrochloride, chlorpheniramine maleate, etc. are mentioned, for example. said eyewashing of these antihistamines -- as a content in liquid, although there is nothing, if especially a limit is diphenhydramine hydrochloride, it is desirable to usually carry out 0.0001-0.05 w/v% content, and it is more desirable. [0.001 - 0.005 w/v% of] If it is chlorpheniramine maleate, it is desirable to usually carry out 0.00001-0.03 w/v% content, and 0.0005 - 0.003 w/v% is more desirable. Unless said each content fulfills said desirable numerical range, while the drug effect by making a drug contain may not be obtained, when said desirable numerical range is exceeded, a feeling of use may be spoiled.

[0015] As said vitamins, flavin adenine dinucleotide sodium, cyanocobalamine, retinol acetate, retinol palmitate, pyridoxine hydrochloride, Panthenol, calcium pantothenate, sodium pantothenate, tocopherol acetate, etc. are mentioned, for example. eyewashing of these vitamins -- as a content in liquid, although there is nothing, if especially a limit is flavin adenine dinucleotide sodium, it is desirable to usually carry out 0.0001-0.05 w/v% content, and it is more desirable. [0.0005 - 0.005 w/v% of] If it is cyanocobalamine, it is desirable to usually carry out 0.0001-0.02 w/v% content, and 0.0002 - 0.002 w/v% is more desirable. If it is retinol acetate or retinol palmitate, 0.0001 - 0.2 w/v%, i.e., do 100-360000I.U. / 100mL content of, is usually desirable, and 0.001 - 0.03 w/v%, i.e., 1000-54000I.U./100mL, is more desirable.

[0016] As said retinol palmitate, the thing of 1 million to 1,800,000 international unit (following I.U. and brief sketch) is usually marketed, and, specifically, retinol palmitate

1,700,000 I.U. (made in Roche vitamin Japan, Inc.) etc. is mentioned. As pyridoxine hydrochloride, it is usually desirable to carry out 0.0001-0.1 w/v% content, and 0.001 - 0.01 w/v% is more desirable. As Panthenol, calcium pantothenate, or sodium pantothenate, it is desirable to usually carry out 0.0001-0.1 w/v% content, and 0.001 - 0.01 w/v% is more desirable. If it is tocopherol acetate, it is desirable to usually carry out 0.0001-0.05 w/v% content, and 0.0005 - 0.005 w/v% is more desirable. Unless said each content fulfills said each ** better ***** range, while the drug effect by making a drug contain may not be obtained, when said desirable numerical range is exceeded, a feeling of use may be spoiled.

[0017] As said amino acid, potassium L-aspartate, L-asparatic acid magnesium, aminoethylsulfonic acid, sodium chondroitin sulfate, etc. are mentioned, for example. eyewashing of these amino acid -- as a content in liquid, although there is nothing, if especially a limit is potassium L-aspartate or L-asparatic acid magnesium, it is desirable to usually carry out 0.005-1 w/v% content, and it is more desirable. [0.01 - 0.1 w/v% of] If it is aminoethylsulfonic acid, it is desirable to usually carry out 0.005-1 w/v% content, and 0.01 - 0.1 w/v% is more desirable. If it is sodium chondroitin sulfate, it is desirable to usually carry out 0.002-0.5 w/v% content, and 0.005 - 0.05 w/v% is more desirable.

[0018] - other component - as the component of said others -- eyewashing -- various kinds of additives, such as all the buffers usually used for preparation of liquid, a solubilizing agent, an isotonicizing agent, a stabilizing agent, a viscous agent, a chelating agent, pH regulator, and a cool-ized agent, other pharmacological active principles, etc. are mentioned. These can usually be suitably blended in the amount used.

[0019] As said buffer, for example A boric acid or its salts (borax etc.), a citric acid, or its salt (sodium citrate etc.), a phosphoric acid or its salt (phosphoric acid 1 hydrogen sodium and a sodium dihydrogenphosphate --) Dibasic sodium phosphate, a sodium dihydrogenphosphate, a potassium dihydrogenphosphate, etc., Carbonic acid or its salt (a sodium carbonate, sodium hydrogencarbonate), a tartaric acid, or its salt (sodium tartrate etc.), a gluconic acid or its salts (sodium gluconate etc.), an acetic acid or its salt, various amino acid (sodium acetate etc.) (glutamic acid, sodium glutamate, etc.), and fatty tuna -- a meta-mall etc. is mentioned. These may be used by the one-sort independent and may use two or more sorts together. the inside of these -- especially -- a boric acid or its salts (borax etc.), and fatty tuna -- by using a meta-mall etc., since the preservation-from-decay effectiveness improves more, it is desirable. especially -- fatty tuna -- since there are few stimuli and the meta-mall has a good feeling of use, it is desirable.

[0020] As said solubilizing agent, polyoxyethylene sorbitan higher-fatty-acid ester, such as polyoxyethylene higher-fatty-acid ester, such as polyoxyethylene (p= 60) hydrogenated castor oil, and polyoxyethylene (p= 20) sorbitan monooleate, propylene glycol, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0021] As said isotonizing agent, a sodium chloride, potassium chloride, a glycerol, D-mannitol, xylitol, grape sugar, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0022] As said stabilizing agent, disodium edetate, cyclodextrin, a sulfite, a citric acid or its salt, dibutylhydroxytoluene, etc. are mentioned, for example.

[0023] As said viscous agent, a polyvinyl pyrrolidone, hydroxyethyl cellulose, the hydroxypropyl methylcellulose, methyl cellulose, polyvinyl alcohol, hyaluronate sodium, sodium chondroitin sulfate, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0024] As said chelating agent, disodium edetate, a sodium citrate, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0025] As said pH regulator, a hydrochloric acid, a sodium hydroxide, a potassium hydroxide, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0026] As said coolized agent, menthol, camphor, a borneol, a geraniol, etc. are mentioned, for example. These may be used by the one-sort independent and may use two or more sorts together.

[0027] <many physical properties of a penetrant remover> -- said eyewashing -- as acidity or alkalinity (pH) of liquid, pH 5-8 is desirable and pH 5.5-8 is more desirable.

[0028] said eyewashing -- as an osmotic-pressure ratio of liquid, although there is especially no limit, it is desirable to adjust within the limits of 0.85-1.55 (osmotic-pressure ratio for a physiological saline).

[0029] said eyewashing -- as viscosity in 20 degrees C of liquid, although there is especially no limit, its 1 - 100 mPa·s is desirable, its 1 - 20 mPa·s is more desirable, and its 1 - 5 mPa·s is still more desirable.

[0030] a [covering device] -- said covering device -- the shape of a film -- it is -- said eyewashing -- the time of saving liquid -- this -- eyewashing -- liquid -- eyewashing -- it does not leak out of a cup -- as -- eyewashing -- it is desirable to have pasted the opening periphery upper limit of a cup with heat sealing, adhesives, etc. adhesion of a covering device -- the time of use -- eyewashing -- it is desirable to be made as [tear / from the

body of a cup / it / easily], and it is more desirable to paste up in the range of peel strength 200 - 2000 g/cm extent with the class of adhesives or the thermal melting arrival temperature of heat sealing. As these adhesives, polyurethane adhesive etc. is desirable.

[0031] As the quality of the material of said covering device, others, an aluminium sheet, etc. which are various synthetic resin, a natural resin material, etc. are mentioned. as resin, such as various synthetic resin and a natural resin material, -- said eyewashing - the resin currently used as the same medical high polymer ingredient as the quality of the material of a cup described, the resin with which antibacterial was given are desirable. Especially as this covering device, the layered product of the resin sheet layer of these resin and an aluminium sheet layer is desirable. It is preferably [a thing with low permeability] as the quality of the material of said covering device, and specifically more desirable that the light transmittance in the wavelength of 200-380nm is less than 10%.

[0032] As thickness of the covering device of the shape of said film, although there is especially no limit, its about 0.03-0.5mm is desirable.

[0033] [other members] etc. -- as the member of said others etc. -- points, such as the stability of a drug, -- it is -- eyewashing -- the package object which packs tools is desirable. light transmittance [in / it is desirable to consist of the quality of the material with low light transmittance as this package object, and / the wavelength of 200-380nm] consists of the quality of the material which is 10% or less -- more -- desirable - a package object -- eyewashing -- it is desirable that tools are especially packed according to an individual.

[0034] < -- eyewashing -- eyewashing of manufacture > this invention of tools -- as the manufacture approach of tools Although there is especially no limit, for example, add each combination component, such as a drug, to sterile purified water, and it dissolves. It carries out aseptic into a cup (for example, the product made from polyethylene; 2 mL). pH -- adjusting -- eyewashing -- eyewashing after preparing liquid -- furthermore, a film (film which laminated aluminium foil in the shape of sandwiches from both sides with the polyethylene film) -- eyewashing -- approaches, such as carrying out a heat sheet along with opening of a cup, are mentioned.

[0035] < -- eyewashing -- eyewashing of this invention explained more than >, such as an application of tools, -- tools -- eyewashing -- eyewashing which does not have worries about microbial contamination and was excellent in safety since needed to repeat a cup and it was not necessary to use it -- liquid can be offered. Moreover, from side effects, such as an eye stimulus by there being no need of blending antiseptics once since it is a

using-up type, and making antiseptics contain, not arising, a stimulus is low also in the case of symptoms [, such as dry eye,], such as damage, inflammation, etc. of the eye especially produced from wearing of a contact lens, pollinosis, etc., and its safety and effectiveness are highly useful to it.

EXAMPLE

[Example] Although an example and the example of a comparison are shown below and this invention is concretely explained to it, this invention is not limited at all by these examples.

[0037] (Examples 1-2) a formula (loadings of each component: mg/100mL) given in Table 1 -- following -- each component -- sterile purified water -- adding -- dissolving -- pH -- adjusting -- eyewashing -- liquid was prepared. it was obtained -- each -- eyewashing -- the unit douse form made from polyethylene which sterilized 2ml of liquid -- eyewashing -- the film (what laminated aluminium foil in the shape of sandwiches from both sides with the polyethylene film, light transmittance in wavelength:200-380nm: 0%) which filled up the cup (wavelength: light transmittance:0% in 200-380nm, thickness:1.0mm) with the bottom of sterile, and sterilized further -- eyewashing -- it heat sealed so that **** of liquid might not happen. then, eyewashing after saving in one month and under a predetermined environment (25 degrees C, 60%RH, fluorescent lamp (1500LUX)) -- when evaluated about generating of the microorganism in liquid, and the stability of a drug, generating of a microorganism was not accepted but was good. [of the stability of a drug] Moreover, when I had ten persons' panelist use it, the stimulus carried out all ten evaluations that a feeling of use was good, without completely sensing.

[0038]

[Table 1]

処方（成分：mg／100mL）	実施例1	実施例2
グリチルチン酸二カリウム	25	25
マレイン酸クロルフェニラミン	3	3
塩酸ピリトキシシン	10	10
L-アスパラギン酸カリウム	100	100
アミノエチルスルホン酸	20	20
コントロイチン硫酸ナトリウム	40	40
ホウ酸	1500	
ホウ砂	100	
トロメタモール	500	1000
滅菌精製水	適量	適量
希塩酸又は水酸化ナトリウム	適量	適量
pH	7	7

[0039] (Examples 3-9) a formula (loadings of each component: mg/100mL) given in Table 2 -- following -- each component -- sterile purified water -- adding -- dissolving -- pH -- adjusting -- eyewashing -- liquid was prepared. it was obtained -- each -- eyewashing -- the product made from polyethylene which sterilized 2ml of liquid, and the product made from polypropylene -- the product made from polyethylene terephthalate, and the product made from ethylene vinyl acetate -- and each unit dose form made from a polycarbonate -- eyewashing -- a cup (light transmittance in the wavelength of 200-380nm: 0 to 5% altogether) thickness: -- the film (what laminated aluminium foil in the shape of sandwiches from both sides with the polyethylene film --) which filled up with the bottom of sterile in 1.0mm, and sterilized further light transmittance:0% in the wavelength of 200-380nm -- eyewashing -- it heat sealed so that the liquid spill of liquid might not happen. Then, it enclosed with the saccate package object of the polyethylene containing an ultraviolet-rays inhibitor. eyewashing after saving this in one month and under a predetermined environment (25 degrees C, 60%RH, fluorescent lamp (1500LUX)) -- the place evaluated about generating of the microorganism in liquid, and the stability of a drug -- which eyewashing -- also in tools, generating of a microorganism was not accepted but was good. [of the stability of a drug] Moreover, when I had ten persons' panelist use it, the stimulus carried out all ten evaluations that a feeling of use was good, without completely sensing.

[0040]

[Table 2]

処方(g/100g)	実施例						
	3	4	5	6	7	8	9
グリチルリチン酸二カリウム	20	25	25	5	25		10
イフシロン-アミノカプロン酸	200			200		500	100
アラントイン			5		30		
塩化ヘキサリン		1.5		0.1			5
塩化リゾチーム						50*	
塩酸ジフェニトロミン						5	
マレイン酸クロルフェニラミン	1	3		3	0.5		2
フラビンアデニンジヌクレオチドナトリウム					5		1
シアノコハラミン						2	0.4
ハルミチン酸レチノール				10	100		1
塩酸ヒトリキシン		10	10	10	5		2
ハントノール						10	2
酢酸d-α-トコフェロール			5	20	10		0.4
L-アスパラギン酸カリウム			100	20	50		10
アミノエチルスルホン酸			20	5	20	100	50
コントロイチン硫酸ナトリウム			40	10		10	10
ホウ酸	1500	500	1000	300	500	1000	500
ホウ砂	20	50		30		50	40
トロメチール	50	200	300	1000	100	500	50
オキシエチレン(p=80)硬化ヒマシ油				100	150		20
オキシエチレン(p=20)ソルビタンモノオレート			100				
プロピレングリコール		300		200	100	100	500
グリセリン						500	
D-マンニトール					100		100
ブドウ糖						100	500
エデト酸ナトリウム			20	10	100		10
ヒドロキシプロピルメチルセルロース				200			100
メチルセルロース						100	
ポリビニルアルコール						300	300
塩化ナトリウム	200		180	500		200	
レーメントール		5	2	3	5		5
d1-オンフル		2	5	3		10	5
d-ホルネオール		1		3			5
クロロブタノール	100	50		100			200
塩酸または水酸化ナトリウム	適量	適量	適量	適量	適量	適量	適量
滅菌精製水	適量	適量	適量	適量	適量	適量	適量

[0041] In Table 2, "*" shows the titer.

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(54)【発明の名称】 洗眼用具

(57)【要約】

【課題】 カップを繰り返し使用する必要がないため、細菌汚染がなく、安全性が高く、更に、防腐剤を配合する必要がないため、眼に対して低刺激の洗眼用具の提供。

【解決手段】 ユニットドーズ形の洗眼カップ内に、少なくとも薬物を含む洗眼液を有してなり、更に、フィルム状の蓋部を有することを特徴とする洗眼用具である。薬物が、消炎・収斂剤、抗ヒスタミン剤、ビタミン類、及び、アミノ酸類の少なくとも1種である態様、トロメタモールを含む態様、洗眼カップが、波長200nm～380nmにおける光透過率が10%以下の可撓性素材からなる態様、蓋部が、樹脂シート層及びアルミニウムシート層の積層体を含む態様等が好ましい。

【特許請求の範囲】

【請求項1】 ユニットドーズ形の洗眼カップ内に、少なくとも薬物を含む洗眼液を有してなり、更に、フィルム状の蓋部を有することを特徴とする洗眼用具。

【請求項2】 薬物が、消炎・収斂剤、抗ヒスタミン剤、ビタミン類、及び、アミノ酸類の少なくとも1種である請求項1に記載の洗眼用具。

【請求項3】 トロメタモールを含む請求項1又は2に記載の洗眼用具。

【請求項4】 洗眼カップが、波長200nm～380nmにおける光透過率が10%以下の可撓性素材からなる請求項1から3のいずれかに記載の洗眼用具。

【請求項5】 蓋部が、樹脂シート層及びアルミニウムシート層の積層体を含む請求項1から4のいずれかに記載の洗眼用具。

【請求項6】 波長200nm～380nmにおける光透過率が10%以下の包装体で包装された請求項1から5のいずれかに記載の洗眼用具。

【請求項7】 ドライアイ、アレルギー性眼疾患、及び、コンタクトレンズ装着時、の少なくともいずれかに20
おいて用いられる請求項1から6のいずれかに記載の洗眼用具。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、洗眼用具に関し、更に詳しくは、薬物を含む洗眼液を、ユニットドーズ形（一回使いきりタイプ）の洗眼カップ内に充填した洗眼用具に関する。

【0002】

【従来の技術】洗眼は、従来より行なわれている、眼疾患治療又は予防の処置法の一つであり、結膜嚢内の洗浄や殺菌、眼病予防等を目的としている。洗眼に用いられる洗眼液を大きく分類すると、眼の洗浄や殺菌を主目的とする無機塩類・殺菌剤含有タイプ（塩化ナトリウム、塩化カリウム、ホウ酸等の無機塩類、アルキルポリアミノエチルグリシン等の殺菌剤を主成分とするタイプ）、及び、眼病予防を主目的とする薬物含有タイプ（消炎・収斂剤、抗ヒスタミン剤、ビタミン類、アミノ酸類を主成分とするタイプ）、の二タイプが挙げられる。これらのタイプの中でも、従来は、洗浄や殺菌のみを目的とし、無機塩類、殺菌剤等を含有するタイプの洗眼剤が主流であった。しかし近年、技術の発達等に伴い、OA機器の多用による疲れ眼やドライアイ患者、コンタクトレンズの装用者や花粉症等のアレルギーを持つ人などが非常に増加したため、眼病を予防し、更なる症状の悪化防止を主目的とした薬物含有タイプが急速に普及しつつある

【0003】これら薬物含有タイプの洗眼液ユーザー等は、眼にダメージを受けている場合が多く、刺激に対して非常に過敏になっている。従って、使用する洗眼液

は、極力眼に対して刺激がある成分を配合しないように設計するのが好ましい。しかし、製剤の微生物汚染を防止する目的で、従来より用いられて来た防腐剤は、健康な眼に対しては特に問題にならないものの、眼粘膜に刺激を与える物質であり、ダメージを受けた過敏な眼に対しては特に刺激が強く問題があった。

【0004】一方、これら洗眼液は、通常、洗眼液を充填した洗眼剤ボトル及び洗眼カップがセットとして市販されており、洗眼液を適宜付属の洗眼カップに小分けして使用されている。従って、洗眼カップは、洗浄の後繰り返し使用することから、細菌汚染を避けるのは難しく問題があった。特に、洗眼液に含まれる薬物中には、細菌の好適な栄養源となる物質が多いことから、細菌の繁殖が大きな問題となっていた。従って、前述のように、洗眼液に刺激の強い防腐剤を配合せざるをえないという問題があった。

【0005】

【発明が解決しようとする課題】本発明は、前記従来における諸問題を解決し、以下の目的を達成することを課題とする。即ち、本発明は、カップを繰り返し使用する必要がないため、細菌汚染がなく、安全性が高く、更に、防腐剤を配合する必要がないため、眼に対して低刺激の洗眼用具を提供することを目的とする。

【0006】

【課題を解決するための手段】前記課題を解決するための手段としては、以下の通りである。即ち、

<1> ユニットドーズ形の洗眼カップ内に、少なくとも薬物を含む洗眼液を有してなり、更に、フィルム状の蓋部を有することを特徴とする洗眼用具である。

<2> 薬物が、消炎・収斂剤、抗ヒスタミン剤、ビタミン類、及び、アミノ酸類の少なくとも1種である前記<1>に記載の洗眼用具である。

<3> トロメタモールを含む前記<1>又は<2>に記載の洗眼用具である。

<4> 洗眼カップが、波長200nm～380nmにおける光透過率が10%以下の可撓性素材からなる前記<1>から<3>のいずれかに記載の洗眼用具である。

<5> 蓋部が、樹脂シート層及びアルミニウムシート層の積層体を含む前記<1>から<4>のいずれかに記載の洗眼用具である。

<6> 波長200nm～380nmにおける光透過率が10%以下の包装体で包装された前記<1>から<5>のいずれかに記載の洗眼用具である。

<7> ドライアイ、アレルギー性眼疾患、及び、コンタクトレンズ装着時、の少なくともいずれかに用いられる前記<1>から<6>のいずれかに記載の洗眼用具である

【0007】

【発明の実施の形態】以下、本発明について詳細に説明する。本発明の洗眼用具は、ユニットドーズ形の洗眼カ

ップ内に、洗眼液を有してなり、更にフィルム状の蓋部を有し、必要に応じてその他の部材等を有する。

【0008】〔洗眼カップ〕前記洗眼カップは、ユニットドーズ形の洗眼カップである。該洗眼カップの大きさ・形状としては、洗眼液が漏れず、洗眼するのに適する設計であれば特に制限はないが、その開口部周辺が眼窩を覆える程度の大きさで、眼窩周縁部にフィットする形状であるのが好ましい。

【0009】前記洗眼カップの材質としては、各種合成樹脂、天然樹脂素材を使用することができるが、その用途等を考慮すれば、医療用高分子材料として使用されている樹脂が好ましい。また、抗菌性が付与された樹脂等であってもよい。

【0010】前記医療用高分子材料としては、例えば、ポリ塩化ビニル（PVC）（硬質、軟質）、ABS樹脂（汎用、難燃性）、ポリエチレン、ポリカーボネート、エチレンビニルアセテート（EVA）、ポリプロピレン、ポリスチレン、合成ゴム、天然ゴム、メタクリル樹脂、シリコン、シリコンゴム、ポリウレタン、高分子ゲル（天然、人工）、ポリ三フッ化エチレン、熱可塑性エラストマー（TPE）、ポリビニルアルコール、ポリテトラフルオロエチレン、エポキシ樹脂、ポリエチレンテレフタレート、ポリアミド、ポリアセタール、ポリ三フッ化ビニリデン、尿素樹脂、フェノール樹脂、アルキド樹脂、メラミン樹脂、シアノクリレート、及び、アクリル樹脂等が好ましい。これらの中でも、特に、ポリエチレン、エチレンビニルアセテート、ポリプロピレン、ポリエチレンテレフタレート、天然ゴム、合成ゴム、シリコン、ポリ塩化ビニル、メタクリル樹脂、シリコンゴム、ポリウレタン、ポリカーボネート、高分子ゲル（天然、人工）、及び、ポリ三フッ化エチレン等が特に好ましい。

【0011】前記洗眼カップの材質としては、洗眼液における薬物の安定性を考慮すると、波長200～380nmにおける光透過率が10%以下の可撓性素材を用いるのが好ましく、特に、酸化チタン、酸化亜鉛、紫外線防止剤、及び、色素を練合した樹脂や、樹脂と前記物質（酸化チタン、酸化亜鉛、紫外線防止剤、及び色素等）を含む光透過防止層の積層樹脂を用いてもよい。前記洗眼カップの厚みとしては、洗眼時の操作性等を考慮すると、0.01mm～1mmであるのが好ましい。

【0012】〔洗眼液〕前記洗眼液は、少なくとも、薬物を含み、必要に応じてその他の成分を含む。

—薬物—

前記薬物としては、特に制限はないが、例えば、消炎・収斂剤、抗ヒスタミン剤、ビタミン類、及び、アミノ酸類等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0013】前記消炎・収斂剤としては、例えば、イプシロン-アミノカプロン酸、アラントイン、塩化ベルベ

リン、硫酸ベルベリン、アズレンスルホン酸ナトリウム、グリチルリチン酸二カリウム、硫酸亜鉛、乳酸亜鉛、及び、塩化リゾチーム等が挙げられる。該消炎・収斂剤の、前記洗眼液における含有量としては、特に制限はないが、イプシロン-アミノカプロン酸であれば、通常0.01～5w/v%（「質量/容量%」を意味する。以下、同様である。）含有させるのが好ましく、0.1～0.5w/v%がより好ましい。アラントインであれば、通常0.001～0.3w/v%含有させるのが好ましく、0.005～0.03w/v%がより好ましい。塩化ベルベリン又は硫酸ベルベリンであれば、通常0.0001～0.025w/v%含有させるのが好ましく、0.0005～0.0025w/v%がより好ましい。アズレンスルホン酸ナトリウムであれば、通常0.00005～0.02w/v%含有させるのが好ましく、0.0001～0.002w/v%がより好ましい。グリチルリチン酸二カリウムであれば、通常0.001～0.25w/v%含有させるのが好ましく、0.005～0.025w/v%がより好ましい。硫酸亜鉛又は乳酸亜鉛であれば、通常0.001～0.25w/v%含有させるのが好ましく、0.005～0.025w/v%がより好ましい。塩化リゾチームであれば、通常0.001～0.5（力価）含有させるのが好ましく、0.01～0.05（力価）がより好ましい。前記各々の含有量が、前記好ましい数値範囲に満たないと、薬物を含有させることによる薬効が得られないことがある一方、前記好ましい数値範囲を超えると、使用感が損なわれることがある。

【0014】前記抗ヒスタミン剤としては、例えば、塩酸ジフェンヒドラミン、及び、マレイン酸クロルフェニラミン等が挙げられる。これらの抗ヒスタミン剤の、前記洗眼液における含有量としては、特に制限はないが、塩酸ジフェンヒドラミンであれば、通常0.0001～0.05w/v%含有させるのが好ましく、0.001～0.005w/v%がより好ましい。マレイン酸クロルフェニラミンであれば、通常0.00001～0.03w/v%含有させるのが好ましく、0.0005～0.003w/v%がより好ましい。前記各含有量が、前記好ましい数値範囲に満たないと、薬物を含有させることによる薬効が得られないことがある一方、前記好ましい数値範囲を超えると、使用感が損なわれることがある。

【0015】前記ビタミン類としては、例えば、フラビンアデニンジヌクレオチドナトリウム、シアノコバラミン、酢酸レチノール、パルミチン酸レチノール、塩酸ビリドキシン、パンテノール、パントテン酸カルシウム、パントテン酸ナトリウム、及び、酢酸トコフェロール等が挙げられる。これらのビタミン類の、洗眼液における含有量としては、特に制限はないが、フラビンアデニンジヌクレオチドナトリウムであれば、通常0.0001

～0.05w/v%含有させるのが好ましく、0.0005～0.005w/v%がより好ましい。シアノコバラミンであれば、通常0.0001～0.02w/v%含有させるのが好ましく、0.0002～0.002w/v%がより好ましい。酢酸レチノール又はパルミチン酸レチノールであれば、通常0.0001～0.2w/v%、即ち、100～360000I.U./100mL含有させるのが好ましく、0.001～0.03w/v%、即ち、1000～54000I.U./100mLがより好ましい。

【0016】前記パルミチン酸レチノールとしては、通常100万～180万国際単位（以下I.U.と略記）のものが市販されており、具体的には、パルミチン酸レチノール170万I.U.（ロシュ・ビタミン・ジャパン株式会社製）等が挙げられる。塩酸ピリドキシンとしては、通常、0.0001～0.1w/v%含有させるのが好ましく、0.001～0.01w/v%がより好ましい。パンテノール、パントテン酸カルシウム、又はパントテン酸ナトリウムとしては、通常0.0001～0.1w/v%含有させるのが好ましく、0.001～0.01w/v%がより好ましい。酢酸トコフェロールであれば、通常0.0001～0.05w/v%含有させるのが好ましく、0.0005～0.005w/v%がより好ましい。前記各含有量が、前記各好ましい数値範囲に満たないと、薬物を含有させることによる薬効が得られないことがある一方、前記好ましい数値範囲を超えると、使用感が損なわれることがある。

【0017】前記アミノ酸類としては、例えば、L-アスパラギン酸カリウム、L-アスパラギン酸マグネシウム、アミノエチルスルホン酸、及び、コンドロイチン硫酸ナトリウム等が挙げられる。これらのアミノ酸類の洗眼液における含有量としては、特に制限はないが、L-アスパラギン酸カリウム又はL-アスパラギン酸マグネシウムであれば、通常0.005～1w/v%含有させるのが好ましく、0.01～0.1w/v%がより好ましい。アミノエチルスルホン酸であれば、通常0.005～1w/v%含有させるのが好ましく、0.01～0.1w/v%がより好ましい。コンドロイチン硫酸ナトリウムであれば、通常0.002～0.5w/v%含有させるのが好ましく、0.005～0.05w/v%がより好ましい。

【0018】—その他の成分—

前記その他の成分としては、洗眼液の調製に通常使用する総ての緩衝剤、溶解補助剤、等張化剤、安定化剤、粘稠剤、キレート剤、pH調整剤、清涼化剤等の各種の添加剤、及び、その他の薬学的有効成分等が挙げられる。これらは、通常使用量において好適に配合することができ

【0019】前記緩衝剤としては、例えば、ホウ酸又はその塩（ホウ砂等）、クエン酸又はその塩（クエン酸ナ

トリウム等）、リン酸又はその塩（リン酸一水素ナトリウム、リン酸二水素ナトリウム、リン酸水素ナトリウム、リン酸二水素ナトリウム、リン酸二水素カリウム等）、炭酸又はその塩（炭酸ナトリウム、炭酸水素ナトリウム）、酒石酸又はその塩（酒石酸ナトリウム等）、グルコン酸又はその塩（グルコン酸ナトリウム等）、酢酸又はその塩（酢酸ナトリウム等）、各種アミノ酸類（グルタミン酸、グルタミン酸ナトリウム等）、及び、トロメタモール等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。これらの中でも、特に、ホウ酸又はその塩（ホウ砂等）、トロメタモール等を使用することにより、防腐効果がより向上するため好ましい。特に、トロメタモールは、刺激が少なく使用感が良好であるため好ましい。

【0020】前記溶解補助剤としては、例えば、ポリオキシエチレン（p=60）硬化ヒマシ油等のポリオキシエチレン高級脂肪酸エステル、ポリオキシエチレン（p=20）ソルビタンモノオレート等のポリオキシエチレンソルビタン高級脂肪酸エステル、プロピレングリコール等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0021】前記等張化剤としては、例えば、塩化ナトリウム、塩化カリウム、グリセリン、D-マンニトール、キシリトール、及び、ブドウ糖等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0022】前記安定化剤としては、例えば、エデト酸ナトリウム、シクロデキストリン、亜硫酸塩、クエン酸又はその塩、ジブチルヒドロキシトルエン等が挙げられる。

【0023】前記粘稠剤としては、例えば、ポリビニルピロリドン、ヒドロキシエチルセルロース、ヒドロキシプロピルメチルセルロース、メチルセルロース、ポリビニルアルコール、ヒアルロン酸ナトリウム、及び、コンドロイチン硫酸ナトリウム等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0024】前記キレート剤としては、例えば、エデト酸ナトリウム、及び、クエン酸ナトリウム等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0025】前記pH調整剤としては、例えば、塩酸、水酸化ナトリウム、及び、水酸化カリウム等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0026】前記清涼化剤としては、例えば、メントール、カンフル、ボルネオール、及び、ゲラニオール等が挙げられる。これらは、1種単独で使用してもよく、2種以上を併用してもよい。

【0027】＜洗淨液の諸特性＞前記洗眼液の液性 p

H)としては、pH5～8が好ましく、pH5.5～8がより好ましい。

【0028】前記洗眼液の浸透圧比としては、特に制限はないが、0.85～1.55（対生理食塩水浸透圧比）の範囲内に調整するのが好ましい。

【0029】前記洗眼液の20℃における粘度としては、特に制限はないが、1～100mPa・sが好ましく、1～20mPa・sがより好ましく、1～5mPa・sが更に好ましい。

【0030】〔蓋部〕前記蓋部は、フィルム状であって、前記洗眼液を保存している際、該洗眼液が洗眼カップ外に漏れないよう、洗眼カップの開口部周縁上端に、ヒートシールや接着剤等によって接着されているのが好ましい。蓋部の接着は、使用時に洗眼カップ本体から容易に引き剥がすことができるようになされるのが好ましく、接着剤の種類やヒートシールの熱融着温度により、剥離強度200～2000g/cm程度の範囲で接着するのがより好ましい。該接着剤としては、ポリウレタン系接着剤等が好ましい。

【0031】前記蓋部の材質としては、各種合成樹脂、天然樹脂素材等のほか、アルミニウムシート等が挙げられる。各種合成樹脂、及び、天然樹脂素材等の樹脂としては、前記洗眼カップの材質で述べたのと同様の医療用高分子材料として使用されている樹脂、抗菌性が付与された樹脂等が好ましい。該蓋部としては、これらの樹脂の樹脂シート層及びアルミニウムシート層の積層体が特に好ましい。前記蓋部の材質としては、透過率が低いのが好ましく、具体的には、波長200～380nmにおける光透過率が10%未満であるのがより好ましい。

【0032】前記フィルム状の蓋部の厚みとしては、特に制限はないが、0.03～0.5mm程度が好ましい。

【0033】〔その他の部材等〕前記その他の部材等としては、薬物の安定性等の点で、洗眼用具を包装する包装体等が好ましい。該包装体としては、光透過率の低い材質からなるのが好ましく、波長200～380nmにおける光透過率が10%以下である材質からなるのがより好ましく、包装体によって、洗眼用具が個別に包装されているのが特に好ましい。

【0034】＜洗眼用具の製造＞本発明の洗眼用具の製

造方法としては、特に制限はないが、例えば、薬物等の各配合成分を滅菌精製水に加えて溶解し、pHを調整して洗眼液を調製した後、洗眼カップ（例えば、ポリエチレン製；2mL）内に無菌充填し、更に、フィルム（アルミニウム箔を、ポリエチレンフィルムで両側からサンドウィッチ状にラミネートしたフィルム）を、洗眼カップの開口部に沿ってヒートシートする等の方法が挙げられる。

【0035】＜洗眼用具の用途等＞以上説明した本発明の洗眼用具は、洗眼カップを繰り返し使用する必要がないため、微生物汚染の心配がなく安全性に優れた洗眼液を提供できる。また、一回使いきりタイプであることから、防腐剤を配合する必要性が無く、防腐剤を含有させることによる眼刺激等の副作用が生じないことから、特に、コンタクトレンズの装着や花粉症等から生じた眼の損傷・炎症など、更には、ドライアイ等の症状の際にも、刺激が低く、安全性・有効性が高く有用である。

【0036】

【実施例】以下に、実施例及び比較例を示し、本発明を具体的に説明するが、本発明は、これらの例によって何ら限定されるものではない。

【0037】（実施例1～2）表1に記載の処方（各成分の配合量：mg/100mL）に従い、各成分を滅菌精製水に加えて溶解し、pHを調整して洗眼液を調製した。得られた各洗眼液2mLを、滅菌したポリエチレン製のユニットドーズ形洗眼カップ（波長：200～380nmにおける光透過率：0%、厚み：1.0mm）に無菌下で充填し、更に、滅菌したフィルム（アルミニウム箔をポリエチレンフィルムで両側からサンドウィッチ状にラミネートしたもの、波長：200～380nmにおける光透過率：0%）を、洗眼液の液漏が起らないようにヒートシールした。その後、1ヶ月間、所定環境（25℃、60%RH、蛍光灯（1500LUX））下で保存した後、洗眼液における微生物の発生、薬物の安定性について評価したところ、微生物の発生は認められず、薬物の安定性も良好であった。また、10名のパネラーに使用してもらったところ、10名とも刺激は全く感じることなく、使用感が良好であるとの評価をした。

【0038】

【表1】

処方（成分：mg/100mL）	実施例1	実施例2
グリチルリチン酸二カリウム	25	25
マレイン酸クロロフェニル	3	3
塩酸ピリドキシ	10	10
L-アスコルビン酸カリウム	100	100
アミノ安息香酸	20	20
コトニコチン硫酸ナトリウム	40	40
ホウ酸	1500	
ホウ砂	100	
トロメタモール	500	1000
滅菌精製水	適量	適量
希塩酸又は水酸化ナトリウム	適量	適量
pH	7	7

【0039】（実施例3～9）表2に記載の処方（各成分の配合量：mg/100mL）に従い、各成分を滅菌精製水に加えて溶解し、pHを調整して洗眼液を調製した。得られた各洗眼液2mlを、滅菌した、ポリエチレン製、ポリプロピレン製、ポリエチレンテレフタレート製、エチレンビニルアセテート製、及び、ポリカーボネート製の各ユニットドーズ形洗眼カップ（波長200～380nmにおける光透過率：総て0～5%、厚み：1.0mm）内に無菌下で充填し、更に、滅菌したフィルム（アルミニウム箔をポリエチレンフィルムで両側からサンドウィッチ状にラミネートしたもの、波長200～380nmにおける光透過率：0%）を洗眼液の液漏

れが起こらないようにヒートシールした。その後、紫外線防止剤入りポリエチレンの袋状包装体に封入した。これを1ヶ月間、所定環境（25℃、60%RH、蛍光灯（1500LUX））下で保存した後、洗眼液における微生物の発生、薬物の安定性について評価したところ、何れの洗眼用具においても、微生物の発生は認められず、薬物の安定性も良好であった。また、10名のパネラーに使用してもらったところ、10名とも刺激は全く感じることなく、使用感が良好であるとの評価をした。

【0040】

【表2】

11 処方 (g/100mL)	12 実施例						
	2	4	5	6	7	8	9
グリチルリチン酸二カリウム	20	25	25	5	25		10
イソシコン-アミノカプロン酸	200			300		500	100
アラントイン			5		30		
塩化ベンズルリン		1.5		0.1			5
塩化リゾチーム						50*	
塩酸ジフェニルピラミン						5	
マレイン酸クロロフェニラミン	1	2		3	0.5		2
フラビニルアチニルヌクレオチルナトリウム					5		1
シアノコハラミン						2	0.4
カルギン酸リチノール				10	100		1
塩酸ピリリキシン		10	10	10	5		2
カンテロール						10	2
酢酸d-α-トコフェロール			5	20	10		0.4
レーアスハラキシン塩カリウム			100	20	50		10
アミノエチルニコチン酸			20	5	20	100	50
ゴットロイシン塩酸ナトリウム			40	10		10	10
ホウ酸	1500	500	1000	300	500	1000	500
ホウ砂	20	50		30		50	40
トロメモール	50	200	300	1000	100	500	50
α-リキエチレン(p=80)硬化ヒマシ油				100	150		20
α-リキエチレン(p=20)ソルビタンモノオレエート			100				
ブロビレングリコール		300		200	100	100	500
グリセリン						500	
D-マンニトール					100		100
ブドウ糖						100	500
エデト酸ナトリウム			20	10	100		10
ヒドロキシアロキルメチルアルコール				200			100
メチルアルコール						100	
α-リビニルグリコール						300	300
塩化ナトリウム	200		180	500		200	
l-メントール		5	2	3	5		5
d1-カンフル		2	5	3		10	5
d-カンフル		1		3			5
クロロブタノール	100	50		100			200
塩酸または水酸化ナトリウム	適量	適量	適量	適量	適量	適量	適量
滅菌精製水	適量	適量	適量	適量	適量	適量	適量

【0041】表2において、「*」は力価を示す。

【0042】

【発明の効果】本発明によれば、カップを繰り返し使用*

*する必要がないため、細菌汚染がなく、安全性が高く、
更に、防腐剤を配合する必要がないため、眼に対して低
刺激の洗眼用具を提供することができる。

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